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SUBJECT: NIGERIAN DRUG REGULATOR CLAIMS COUNTERFEITING SUCCESS

¶1. Summary: Professor Dora N. Akunyili has transformed Nigeria's National Agency for Food, Drug Administration and Control (NAFDAC) into an effective regulatory agency. NAFDAC has reduced the number of counterfeit drugs on the market, increased surveillance at ports, streamlined drug registration processes and established the National Pharmaceutical Vigilance Center. Despite attempts on her life and the lives of NAFDAC employees, threats, blackmail and attacks on almost all NAFDAC offices, Dr. Akunyili claims NAFDAC is nearly corruption free. End Summary.

A CHAIN REACTION

¶2. In a speech to an International Visitor Leadership Program seminar on "Challenges of Leadership in Nation Building" Dr. Akunyili described the progress of creating an effective food and drug regulatory agency in Nigeria. When she was appointed head of NAFDAC, counterfeit drugs had eroded the public confidence in health care and food delivery systems. In 2001, 68 percent of drugs in Nigeria were unregistered and almost all were counterfeited, especially the three most commonly used drugs (vitamins, antibiotics and anti-malarials). Counterfeiting also extended to food and cosmetics. Dr. Akunyili's own sister died when she was treated with counterfeit insulin. The counterfeiting greatly damaged legitimate local drug producers and some multinationals left Nigeria. Additionally, drugs made in Nigeria were banned from other West African countries.

¶3. According to Dr. Akunyili, corruption at NAFDAC was extensive and present at all levels of production and procurement. Both NAFDAC and the local industry suffered from a lack of awareness of drug safety, sophisticated counterfeiting technology, and a chaotic distribution system.

NAFDAC BATTLES INTERNAL CORRUPTION

¶4. Dr. Akunyili's approach to reform focused on NAFDAC's employees. In addition to extensive staff training at all levels, NAFDAC itself was reorganized. Corrupt employees were fired and NAFDAC downsized. Performance evaluations were implemented while employee benefits were increased. NAFDAC officials caught aiding or abetting corrupt companies are immediately dismissed. In addition to staff changes, five laboratories were upgraded, three new laboratories were developed, and new land border offices were built.

PUBLIC AWARENESS IS KEY

¶5. One of NAFDAC's most effective tools, says Dr. Akunyili, in combating counterfeiting has been a public awareness campaign. NAFDAC wanted to make as many people as possible aware of its vision, including staff, industry, consumers, the government and other stakeholders. They used a combination of print and electronic media, workshops and seminars, an annual essay competition for high schools, and the "Green Pages" booklet which provide information on all NAFDAC-registered products and related contact information. According to Akunyili, the public education campaign has had success in changing the behavior of stakeholders.

NAFDAC PUSHES FOR STRONGER LAWS

¶6. Nigerian laws against counterfeiting are weak. Dr. Akunyili claims some criminals have shifted from the gun and narcotics trade to counterfeit pharmaceuticals, a lower risk and equally lucrative business. In Nigeria, the penalty for producing, importing, or distributing fake drugs/regulated products is either a three-month to five-year prison term or a fine of 10,000-500,000 naira (currently \$80.26-\$4132.00). NAFDAC reviewed the laws and submitted proposed changes to the National Assembly in 2001. [Note: No laws have yet been changed. End Note]

NAFDAC BATTLES CORRUPTION IN COURTS

¶7. According to Akunyili, counterfeiters use the legal system to delay and circumvent justice typically through the granting of injunctions. NAFDAC has four pending cases against a local pharmaceutical firm from drug seizures in 1996 through 1998 but a

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series of court injunctions blocked further charges. Another court ordered NAFDAC to return drugs seized from Vipfarm Industries. The company then filed a criminal complaint against NAFDAC officials for false charges and asked for \$4.6 million in "interest" on the value of the drugs seized. The case is still pending.

SUCSESSES TO DATE

¶8. Akunyili claims her agency has achieved these milestones:
--Implemented regular monitoring of manufacturers;
--Established a National Pharmacovigilance Center;
--Initiated the West African Drug Regulatory Authorities Network;
--Begun enforcement of prescription-based issuance of drugs;
--Reduced counterfeit drugs in circulation from more than 41 percent in 2001 to 16.7 percent in 2006. [Note: This number is disputed by some pharmaceutical companies who estimate that 80 percent of drugs on the market are counterfeit. End Note.];
--Reduced unregistered drugs on the market from 68 percent in 2001 to 19 percent in 2006;
--Removed the West African ban on drugs made in Nigeria;
--Destroyed 115 counterfeit and substandard product shipments, valued at \$1.5 million, and;
--Obtained convictions in 45 counterfeit cases with 60 additional cases in the courts.

DEATH THREATS, VIOLENCE AS CRIMINALS RESIST REGULATORS

¶9. This effort comes at considerable risk to the employees and properties of NAFDAC, as the counterfeiters have fought back beyond the legal system. Bribery attempts, harassment, blackmail, and threats of violence have all been reported, according to Akunyili. NAFDAC staff and facilities have been physically attacked. In 2002, the NAFDAC lab in Lagos was vandalized and its equipment destroyed. In 2003, Akunyili's son was kidnapped and her car was shot at with bullets grazing her skull through her headscarf. In 2006 and 2007,

NAFDAC officers were driven out of Onitsha and Kano markets by drug counterfeiters. Dr. Akunyili is guarded by at least eight policemen.

¶10. Comment: Though Dr. Akunyili presents a positive picture of anti-drug counterfeiting efforts in Nigeria, others in the pharmaceutical industry are less optimistic. A walk through any Nigerian open air market will reveal a wide variety of prescription drugs, or counterfeit drugs, for sale. While her success is certainly remarkable, much remains to be done to combat the counterfeiters. End Comment.